IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

DAYTON AREA CHAMBER OF COMMERCE; OHIO CHAMBER OF COMMERCE; MICHIGAN CHAMBER OF COMMERCE; and CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

No. _____

DECLARATION OF MICHAEL C. STAFF IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, Michael C. Staff, declare as follows:

1. I am Vice President, Inflation Reduction Act (IRA) Product and Channel Strategies, for AbbVie Inc. ("AbbVie").

2. AbbVie is a member of the Chamber of Commerce of the United States of America and the Dayton Area Chamber of Commerce, Plaintiffs in this action.

3. AbbVie is a global research-based biopharmaceutical company. AbbVie develops and markets innovative therapies that address some of the world's most complex and serious diseases. AbbVie's comprehensive product portfolio has leadership positions across immunology,

oncology, aesthetics, neuroscience, and eye-care. AbbVie invests billions of dollars annually to pursue new advanced treatments in these and other areas.

4. AbbVie participates in federal healthcare programs, including Medicare Part D and Medicaid. As a participant in Medicare Part D, AbbVie is subject to the provisions of "Inflation Reduction Act of 2022," 42 U.S.C. §§ 1320f *et seq*. (the "IRA"). The IRA requires the Secretary of the Department of Health and Human Services to select certain pharmaceutical drugs to be subject to a statutorily prescribed price-setting process for the Medicare Part D program.

5. Specifically, for the initial price applicability year (2026) under the IRA, the IRA requires the Secretary to select the ten Part D qualifying single source drugs with the highest Part D gross expenditures from June 1, 2022, through May 31, 2023. Although the information from that period is not yet available, the most recent data made publicly available (for plan year 2021) by the Centers for Medicare & Medicaid Services, an agency of the Department of Health and Human Services, in its Drug Spending Dashboard include IMBRUVICA®, one of AbbVie's current on-market products, among these drugs with the top ten gross annual Part D expenditures (https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug). Market observers are predicting that IMBRUVICA® will be among the ten drugs selected by the Secretary for the IRA's price-setting process by September 1, 2023. For example, on March 13, 2023, the news agency Reuters published an article titled "Bristol Myers, Pfizer, AbbVie drugs likely to face U.S. price negotiation." The article stated that "AbbVie's leukemia treatment Imbruvica [is] likely to be among 10 big-selling medicines subject to U.S. price negotiations [under the IRA] in 2026, according to five Wall Street and academic analyses shared with Reuters." Michael Erman et al., *Bristol Myers, Pfizer, AbbVie drugs likely to face U.S. price negotiation*, Reuters.com (March 13, 2023), https://reut.rs/3pQgPmH.

6. Selection by the Secretary of a drug for price-setting means that starting on October 1, 2023, the drug's manufacturer will be forced to enter into a so-called "negotiation" process with the Secretary, who will then impose a price for the drug. These will not be true "negotiations" in any ordinary sense of the word because the IRA forces manufacturers to participate on pain of massive penalties. And rather than seek a fair mutual bargain, Congress directed the Secretary to set a price that is no higher than a statutory ceiling price and "to achieve the *lowest* maximum fair price for each selected drug." 42 U.S.C. § 1320f–3(b)(1) (emphasis added). In circular fashion, the IRA defines the term "maximum fair price" not by reference to any standard of fairness, but simply as the price determined by the Secretary. *See id.* § 1320f.

7. The IRA is already harming manufacturers like AbbVie now. As the government acknowledged in recent guidance, "manufacturers need to take a number of actions well in advance of September 1, 2023, to prepare for the possibility that a drug that they manufacture will be included on the selected drug list for initial price applicability year 2026," including devoting financial and human resources to "review[ing] the template Medicare Drug Price Negotiation Program Agreement and guidance to understand Negotiation Program requirements for participating manufacturers in advance of the statutory deadline of October 1, 2023, for entering agreements, and gather[ing] information for potential submission to CMS by the statutory deadline of October 2, 2023." June 30, 2023, Memorandum from Department of Health and Human Services, Centers for Medicare & Medicaid Services re: Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2026, https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf, at 9. AbbVie has already begun committing resources to these activities.

8. The irreparable harm from the IRA's "negotiation" regime will become especially concrete and acute by October 1, 2023, when manufacturers of selected drugs are required to sign a non-negotiable "agreement" with the Secretary to accept whatever price the Secretary ultimately chooses. The template "agreement" released by CMS on July 3, 2023, makes clear that manufacturers will not be compensated for any losses incurred as a result of the "agreement" and that CMS can unliterally "amend" the "agreement" at any time. *See* CMS, Template "Medicare Drug Price Negotiation Agreement" at 4, https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf.

9. The *day after* those "agreements" are signed—October 2, 2023—manufacturers will be required to submit extensive and detailed information to the Secretary. By statute, the Secretary can demand this information from manufacturers, including confidential and proprietary information that AbbVie would not ordinarily disclose to another market participant or contracting counterparty, all "in a form and manner specified by the Secretary." 42 U.S.C. § 1320f–2(a)(4). AbbVie would have to give proprietary and trade secret information to the Secretary, such as detailed research and development costs; market data for the drug; and costs of production and distribution. *Id.* § 1320f–2(a)(4)(B), (e)(1). And AbbVie would have to provide all that information under the threat of $1 million-per-day penalties if the Secretary believed AbbVie has not timely provided all the information he demanded. *Id.* §§ 1320f–2(a)(4)-(5), 1320f–6(b).

10. This "agreement" would also risk injurious effects in other markets, including the commercial drug market. Long before the government's price controls take effect in 2026, the government must publish the so-called "maximum fair prices" by September 1, 2024. The IRA forces manufacturers to agree that the Secretary's imposed prices are the "maximum fair prices,"

an endorsement that would likely cause a loss of customer goodwill, due to the inevitable comparison with the market-based, competitively determined prices that prevail today..

11. The IRA also impinges on AbbVie's First Amendment rights by depriving AbbVie of choice in what it says – and does not say – about the price-setting process. For instance, the IRA would compel AbbVie to endorse the government's misleadingly chosen message that the price-setting process is a "negotiation," compels AbbVie to sign a "negotiation agreement" the terms of which AbbVie has no ability to disagree with, and to call the Secretary's unilaterally-determined price the "maximum fair price" for IMBRUVICA®, even though that message is false and inconsistent with AbbVie's own views.

12. AbbVie also faces imminent injury in the impairment of its reasonable investment-based expectations in a fair market price for IMBRUVICA® without adequate safeguards for the fairness of the price-setting process. AbbVie paid approximately $21 billion to acquire Pharmacyclics, of which IMBRUVICA® was the flagship asset. When AbbVie decided to make that investment in IMBRUVICA®, it did so expecting that future market-based revenues from IMBRUVICA® would pay for the acquisition costs, pay for additional R&D investment to develop IMBRUVICA® as a treatment for additional types of cancers, and help pay for the billions of dollars that AbbVie invests annually in research initiatives to develop new cures and treatments for serious diseases, the vast majority of which fail and never yield a successful on-market medicine. The IRA would force IMBRUVICA®'s price down by imposing a maximum ceiling price that would be significantly lower than IMBRUVICA®'s current market price, and it further directs the Secretary to achieve the "lowest" price possible for selected drugs, with no requirement that the Secretary provide even a just and reasonable return on AbbVie's investment. The IRA

then prohibits AbbVie from seeking judicial review of the Secretary's imposed price for IMBRUVICA®.

13. Although the IRA labels its price-setting process a "negotiation," the statute permits the Secretary to unilaterally set a selected drug's price below an agreed-upon market price. Specifically, the Medicare Part D price set by the Secretary for IMBRUVICA® would necessarily be lower than IMBRUVICA®'s current market price. The IRA establishes a ceiling price for the drug through a formula that requires a price below the current market price. Moreover, the statute provides no guidance for the Secretary as to how to set the price below that ceiling, except to strive for the "lowest" price. The IRA also provides no minimum "floor" price that would guarantee a fair return on investment and avoid confiscatory pricing for IMBRUVICA®.

14. These aspects of the IRA scheme – the work needed even before the September 1, 2023, publication of the list of selected drugs to review the agency's guidance and templates and to collect data to prepare for the possibility that a drug will be on the September 1 list; the unilateral price reduction with no limitations on the Secretary to avoid confiscatory pricing; the deprivation of judicial review of the fairness of that reduction; the loss of AbbVie's reasonable investment-based expectation of a market-based price; the compelled speech endorsing the government's viewpoint concerning this supposed "negotiation" program; and the spillover effect in commercial markets – would each cause harm to AbbVie. Because of the government's sovereign immunity, AbbVie could not recover damages from the government to compensate for these costs and harms. See CMS, Template "Medicare Drug Price Negotiation Agreement" at 4 ("Actions by the Manufacturer for damages are not permitted pursuant to this Agreement."), https://www.cms.gov/files/document/inflation-reduction-act-manufacturer-agreement-template.pdf.

15. Pharmaceutical companies, including AbbVie, would have no practical ability to avoid this price-setting process. In theory, there are only two ways for a company whose drug is selected to avoid the "negotiation" process that exposes it to potentially confiscatory pricing: (i) refuse to engage in the price-setting process and pay a massive "excise tax," or (ii) withdraw entirely from federal healthcare programs. Neither option would be tenable.

16. First, the so-called "excise tax" is a confiscatory penalty that is literally unbearable — it starts at 65% of the drug's total post-tax price and applies to all sales (not just those in federal health care programs) and increases quarter-by-quarter until it ultimately reaches 95% of the drug's total post-tax price. This statutory formula means that if a manufacturer refuses to "agree" to negotiate or later refuses to accept the government-imposed "maximum fair price," the manufacturer would be required to pay penalties on a scale that rapidly escalates to 1900% of the drug's pre-tax price, meaning that a drug that previously sold for $100 per unit would be subject to a "tax" of $1,900 per unit, for a total price of $2,000 (of which the "tax" represents 95%). That is an unbearably high price for refusing to "agree" to provide access to AbbVie's drugs at whatever price the Secretary imposes.

17. Second, that excise tax would be applied for some time even if AbbVie attempted to withdraw all of its drugs from Medicare Part D and Medicaid to avoid being exposed to confiscatory pricing for IMBRUVICA®. By statute, it is impossible for any company whose drugs are selected for "negotiation" to decide against participating and withdraw from Medicare Part D and Medicaid before the statute's excise tax begins to be imposed.

18. Third, as a practical matter, to avoid the excise tax, the IRA requires a manufacturer to withdraw all of its drugs from Medicare and Medicaid. For AbbVie, this would mean that, to avoid being exposed to confiscatory pricing for IMBRUVICA®, it would have to withdraw not

only IMBRUVICA® but also the more than 85 other AbbVie products currently covered by Medicare and/or Medicaid from patients in those programs who depend on those AbbVie products. That is not a realistic option. Medicare and Medicaid account for a huge share of the healthcare market. In 2021, for example, Medicare accounted for 21% of national health spending and Medicaid for 17%. In comparison, private health insurance accounted for only 28% of national health spending. See NHE Fact Sheet, Historical NHE, 2021, CMS.gov, https://go.cms.gov/41mwXL8.

19. The IRA would thus effectively force AbbVie to participate in the IRA's price-setting process, depriving it of any true choice whether to participate or not.

Pursuant to 28 U.S.C. §1746, I declare that the foregoing is true and correct.

Executed this 11th day of July, 2023.

Michael C. Staff